Cox proportional hazard model, there were an improvement of local-regional relapse-free survival (p = 0.0050), and a trend of better overall survival (p = 0.0762) with the use of adjuvant chemoradiotherapy. In a subgroup analysis on patients with nodal involvement (n = 38), the use of chemoradiotherapy was correlated with increased overall and local-regional relapse-free survival on multivariate analysis (p = 0.0235 and 0.0095, respectively). The benefit of adjuvant chemoradiotherapy was significant for local-regional relapse-free survival (p = 0.0319), but not for overall survival (p = 0.4544) in patients with T3/T4 disease (n = 40).
Conclusions: Adjuvant chemoradiotherapy enhances locoregional control, and possibly overall survival in patients with ampulla of Vater cancer after curative resection.

3552 POSTER

Impact of the body mass index on the outcome of patients with cancer of the esophagogastric junction after surgical resection

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According to the classification of Siewert, cancer of the gastroesophageal junction is subdivided into Type I, II, or III dependent on its localization. Type I cancers are considered to be distal esophageal cancers, which are treated with esophageal resection. Type II and III cancers are considered to be gastric cancers and are treated with extended gastrectomy including resection of the distal esophagus. We were interested to evaluate the impact of body mass index (BMI) on postoperative complications, length of stay in the ICU, total hospital stay, and overall survival.
From 2000 to 2006, 108 patients with cancer of the esophagogastric junction were operated in our department. We divided the patients into two groups according to BMI. Fifty-six patients (52%) presented with a BMI below 25 kg/m2 (group 1) and fifty-two patients (48%) above 25 kg/m2 (group 2). Type I cancers (n = 26; 24%) were equally distributed between groups 1 and 2 with 13 patients in each group. Type II cancers (n = 61; 56%) were the most frequent types and occurred more often in group 2 (34 vs 27), and Type III cancers (n = 21; 19%), had a higher prevalence in group 1 (16 vs 5).
Pulmonary complications were observed in 33 patients (respiratory in sufficiency n = 12, pneumonia n = 12, bronchitis n = 7, lung embolism n = 2). There was no statistically significant difference between groups 1 and 2. However, both lung embolisms were seen in group 2. Eighteen patients developed surgical complications (anastomotic leakage n = 7, chylus fistula n = 1, intraabdominal abscess n = 3, intrapleural abscess n = 2, abscess of the abdominal wall n = 3, and bleeding n = 2). There was also no statistically significant difference between groups 1 and 2. Functional complications occurred in 29 patients (dysphagia n = 5, nausea n = 5, heart burn n = 4, impaired enteral nutrition n = 6, vomiting n = 9). We found no statistically significant difference between groups 1 and 2. However, impaired enteral nutrition and vomiting was observed more frequent in group 2. The median time in the ICU was 3 days in group 1, and 5 days in group 2 (p = 0.021). The median hospitalization time was 14 days in both groups. Overall survival after a follow up of 42 months was 34% in group 2 and 25% in group 1 (p = 0.961). Recurrence free survival was 48% in group 1 and 42% in group 2 (p = 0.596).
Our data show that surgery for cancer of the cardia can be performed independent of the BMI.

3553 POSTER

Phase I/II study of S-1 in patients (pts) with advanced hepatocellular carcinoma (HCC): Results of phase I part – Correlation between pharmacokinetics (PK) and hepatic dysfunction

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Background: S-1 is an oral formulation combining tegafur (FT), gimeracil (CDHP), and oteracil potassium (Oxo). The standard dose is 80 mg/m^2 bid for gastrointestinal, head and neck, breast, and lung cancers in Japan. The liver plays an important role in the conversion of FT to 5-FU, as well as the degradation of 5-FU. S-1 is expected to be effective against HCC, but nearly all pts with HCC have hepatic dysfunction. This study was designed to examine the correlation between the PK of S-1 and hepatic dysfunction and to determine the recommended dose of S-1 for pts with advanced HCC. In addition, we compared PK parameters in pts with HCC with those in patients with pancreatic cancer (PC) and biliary tract cancer (BTC).
Materials and Methods: Eligibility criteria were advanced HCC, unresectable/incurable by ablation or TACE, pathological and/or clinical confirmation of the diagnosis, at least one measurable lesion, an ECOG performance status (PS) of 0 to 2, Child-Pugh class A or B, adequate organ functions, and written consent. The starting dose of S-1 (level 1) was about 64 mg/m^2 bid (80% of standard dose) on days 1−28 of a 42-day cycle. Level 2 was 80 mg/m^2. A standard 3+3-design and standard definitions of DLT were employed. PK analyses were performed to determine the plasma concentrations of the S-1 components (FT, CDHP, and Oxo) and 5-FU on days 1 and 8. The PK parameters were compared with those in 8 pts with PC and 8 pts with BTC who were enrolled in each phase II trial.
Results: Nine pts with HCC (level 1: 3 pts, level 2: 6 pts), including 3 with Child-Pugh class B were enrolled. All pts had a PS of 0. The most common toxicities were thrombocytopenia, leukopenia, neutropenia, and anorexia. > Grade 3 toxicity was rare. There was no DLT at level 1. At level 2, DLT occurred in 2 pts with Child-Pugh class B. One had grade 3 anorexia, and the other had grade 2 rash, requiring more than 8 consecutive days of rest. There were no significant differences in PK parameters among pts with Child-Pugh class A, B, and the 16 pts with PC and BTC. Two pts (level 1: 1 pt, level 2: 1 pt) had a partial response, giving an overall response rate of 22% (2/9).
Conclusions: Hepatic dysfunction (Child-Pugh class A or B) did not significantly affect the PK parameters of S-1 or its metabolites. Although S-1 should be carefully given to pts with Child-Pugh class B, S-1 at 80 mg/m^2 bid is tolerated in pts with advanced HCC. This dose is recommended for the phase II part of this study.

3554 POSTER

Phase II study of oxaliplatin with low dose leucovorin and bolus and continuous infusion 5-fluorouracil (Modified FOLFOX-4) for gastric cancer patients with malignant ascites

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Background: The clinical study about chemotherapy of gastric cancer patients with malignant ascites had limited because peritoneal seeding is not defined measurable lesion and generally patients had poor performance status. We evaluate the efficacy and toxicity of fortnightly modified FOLFOX-4 regimen in patients with peritoneal disseminated gastric cancer.
Methods: Gastric cancer patients who had cytologically confirmed malignant ascites were treated with cycles of oxaliplatin 85 mg/m^2 on day 1 plus leucovorin 20 mg/m^2, followed by 5-FU a 400 mg/m^2 bolus and a 22 hour continuous infusion of 600 mg/m^2 5-FU on days 1−2 every 2 week intervals.
Results: Forty-eight patients were enrolled in this study. Male to female ratio was 2:1. Median age was 47 (31−76). 22 patients (45.8%) were treated with modified FOLFOX-4 as a 1st line palliative treatment. 21 patients (43.8%) had ECOG performance status 2. 36 patients were assessable with measurable lesion. Twelve of the 36 patients demonstrated partial responses (PR). Ascties amount decreasing or disappearance was observed 17 (35.4%) patients. The median time to progression and overall survival time were 3.5 months (95% CI: 2.9−4.1 months) and 8.4 months (95% CI: 4.9−11.9 months), respectively. Totally 233 cycles of chemotherapy were done. Major hematologic toxicities included grade 1−2 anemia (53.9%), neutropenia (41.6%) and grade 3−4 neutropenia (15.8%). Six cycles were associated with neutropenic fever. The most common non-hematological toxicities were grade 2 and 3 nausea/vomiting (17%). There was no treatment related death.
Conclusion: Even though gastric cancer patient with malignant ascites accompanied poor performance status, modified FOLFOX-4 regimen was found to be a safe and effective.

3555 POSTER

The efficacy of early ^{18}F-fluorodeoxyglucose positron emission tomography following completion of definitive chemoradiotherapy in patients with esophageal carcinoma

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Background: To assess the value of early ^{18}F-fluorodeoxyglucose positron emission tomography (FDG-PET) scans following definitive chemoradiotherapy (CRT) in predicting clinical local response (CLR) or local relapse-free survival (LRFS) of esophageal cancer patients.
Methods and Materials: We retrospectively analyzed 25 esophageal cancer patients who were treated with curative CRT between January 2005 and December 2006. Median age of patients was 60 years (range,

48−84 years). Informed consent was obtained from all patients. Underlying pathology was squamous cell carcinoma (n = 24, 96%) and malignant melanoma (n = 1, 4%). The median total dose of radiotherapy to the primary tumor was 65 Gy (range, 60–70 Gy) given in 1.8 or 2.0 Gy single daily fractions. All patients were treated with concurrent chemotherapy consisting of two cycles of cisplatin or nedaplatin combined with 5-FU or docetaxel. All patients underwent FDG-PET scanning within several days of CRT completion. Maximum standardized uptake value (maxSUV) at the primary site was evaluated for CLR and LRFS in univariate and multivariate analyses. P values <0.05 were considered significant.
Results: See Table 1. Univariate analysis revealed that maxSUV cutoff values of 3.5 (P = 0.042) and 6.5 (P = 0.024) were significantly associated with CLR. Multivariate analyses showed that maxSUV > 3.5 was predictive of CLR. The log-rank test found that maxSUV cutoff values of 3 (P = 0.02), 3.5 (P = 0.014), 6.5 (P = 0.004), and 7 (P = 0.034) were related to LRFS. The multivariate Cox model revealed that maxSUV > 3.5 was significantly correlated with LRFS.
Conclusions: Early FDG-PET scans following curative CRT appears to be valuable in evaluating CLR and LRFS in esophageal cancer patients.

Table 1. Post-CRT FDG-PET assessment of clinical response at primary site[a]

SUV criteria	Sens. (%)	Spec. (%)	Accuracy (%)	P value	
				Univar.	Multivar.
SUV >2.0 vs. ⩽2.0	100	6	36	NS	NS
SUV >2.5 vs. ⩽2.5	100	18	44	0.527	0.953
SUV >3.0 vs. ⩽3.0	88	53	64	0.088	0.972
SUV >3.5 vs. ⩽3.5	88	59	68	0.042	0.029
SUV >4.0 vs. ⩽4.0	63	59	60	0.411	0.953
SUV >4.5 vs. ⩽4.5	50	65	60	0.667	0.928
SUV >5.0 vs. ⩽5.0	50	71	64	0.394	NS
SUV >5.5 vs. ⩽5.5	50	88	76	0.059	0.941
SUV >6.0 vs. ⩽6.0	38	88	72	0.283	0.946
SUV >6.5 vs. ⩽6.5	38	100	80	0.024	0.928
SUV >7.0 vs. ⩽7.0	25	100	76	0.093	NS

[a]Sens., sensitivity; Spec., specificity; Univar., Univariate analysis; Multivar., multivariate analysis; NS, not significant.

Abbreviations: CRT = chemoradiotherapy; FDG-PET = ^{18}F-fluorodeoxyglucose positron emission tomography; SUV = standardized uptake value.

3556 POSTER

The utility of PET in anal cancer

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Background: Functional imaging is becoming increasingly important in the staging and assessment of cancer patients. The aim of this study was to assess the utility of FDG-PET in anal cancer for staging, treatment response and detection of recurrent disease.
Methods and Materials: A retrospective study was performed on 50 patients that were identified with histopathologically confirmed epidermoid anal cancer referred to the Austin PET Center between 1996–2006. 45 patients were treated with curative intent (radical) mainly with combined chemo-radiation. The remaining 5 patients were treated with radiotherapy alone. PET imaging was initially performed on a Phillips Allegro PET scanner then subsequently on a Phillips Gemini PET-CT scanner from 2003. The median age of the patients was 58 years (36−85 years). The non-PET clinical staging including CT was of 8 Stage I (16%), 18 Stage II (36%), 22 Stage III (44%), and 2 Stage IV (4%) patients. PET was used in staging and following treatment to assess the response and detect recurrent disease. The PET results were correlated with clinical and pathological findings.
Results: Pre-treatment PET staging was performed in 48 patients. The primary tumor was excised in 7 patients and the PET scan was negative at primary site in all. In the 41 patients with a non-excised tumour, the primary tumor was strongly FDG avid in 40 (98%) patients compared to CT which detected 58%. PET upstaged 8 (17%) patients with unsuspected pelvic or inguinal nodal disease and downstaged 3 (6%). Post-treatment PETs were performed in 25 patients (median time of 17 weeks, range 9−28 weeks) of which there were 20 (80%) complete responses (CR) and 5 (20%) partial responses (PR). By 18 weeks, 15 of 16 scans (94%) performed showed a CR. The PRs were biopsy positive in 2 and negative in 3. At last follow-up, 10 of the 45 radical patients (22%) had developed recurrent disease of which 9 had PET scans. In seven patients, the PET scanning was used to confirm recurrence. In the remaining two patients, follow-up PET detected unsuspected recurrence where there was no prior clinical or radiological evidence of disease. All of the 9 PET detected recurrences were pathologically confirmed.
Conclusions: Anal cancer appears to be FDG avid and PET upstages nearly one fifth of patients. Therefore, PET is useful for staging of anal cancer and can assist in the identification of residual disease post-treatment and can aid in the detection of recurrent disease.

3557 POSTER

Phase I study of docetaxel, oxaliplatin and S-1 (DOS) for patients with advanced gastric cancer

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Background: Docetaxel, oxaliplatin and S-1 have shown significant single-agent efficacy in gastric cancer. These drugs have distinct mechanisms of action and no overlapped key toxicities. Furthermore, fluoropyrimidine and docetaxel or oxaliplatin have shown synergism in vivo studies and in clinical trials. We performed a phase I study of combination docetaxel, oxaliplatin and S-1 (DOS) to determine the maximum-tolerated dose (MTD), recommended dose (RD) and efficacy in advanced gastric cancer.
Methods: Eligible patients were those who had unresectable, locally advanced or metastatic, gastric adenocarcinoma. Both initially diagnosed and recurred patients with no previous history of chemotherapy except adjuvant chemotherapy were enrolled. The patients of age 18 to 70 with ECOG PS 0−2 were enrolled to this study. Docetaxel and oxaliplatin were administered intravenously on day 1 and S-1 was administered orally on days 1−14. Cycles were repeated every 21 days. Doses were escalated as follows: docetaxel/oxaliplatin/S-1, level −1A 52.5/80/60; level −1B 52.5/80/80; level 1A 52.5/105/80; level 1B 52.5/130/80; level 2A 60/105/80; level 2B 60/130/80; level 3A 67.5/105/80; level 3B 67.5/130/80; level 4A 75/105/80; and level 4B 75/130/80 (mg/m^2).
Results: Nine patients (male/female 6/3; median age 52, range 39−67; median ECOG PS 0) have been enrolled in this study. Five patients had recurred cancer after surgery and adjuvant chemotherapy and 4 patients were diagnosed as a metastatic disease. Tumor differentiation was 2 moderate, 5 poor and 2 unknown. Main sites of metastasis were 6 liver, 6 lymph node, 8 peritoneum, 1 bone and 2 others. One of 6 patients at level 1A and 2 of 3 patients at level 1B developed dose-limiting toxicity (grade 4 neutropenia with fever) during the initial 2 cycles. Therefore, the dose at level 1B and level 1A were determined as the MTD and RD, respectively. A total of 51 cycles were administered (median 7, range 1−9). All patients were evaluated for toxicity and response. The main toxicities were neutropenia (grade 1/2/3/4 = 0/0/2/7 patients) and neutropenic fever (grade 3 = 4 patients) that were easily manageable. There were 5 PR, 3 SD and 1 PD. The response rate was 56% and the disease control rate was 89%.
Conclusions: These data suggest that DOS regimen is safe and active in patients with advanced gastric cancer. Phase II study with RD will be started.

3558 POSTER

Metastatic small bowel adenocarcinoma: favourable outcome in patients with primary tumour resected – retrospective analysis of 44 cases

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Background: Small bowel Adenocarcinoma (SBA) is a rare disease with probably less than 400 new cases per year in Germany. Only limited data is available concerning the effect of palliative chemotherapy (CT) in this disease. Resection of the primary tumour is not routinely performed if distant metastases are present.
Material and Methods: We retrospectively evaluated the files of all patients (Pt) who received at least one cycle of palliative CT. Pt were classified to have the primary (PRI) or local recurrence (LR) surgically completely removed or not and whether they were offered a 2nd-line CT in case of failure or not.